REMARKS

Applicant has carefully reviewed the Final Office Action mailed February 3, 2009, and the Advisory Action mailed April 3, 2009, prior to preparing this response. Currently claims 1-13 and 19-26 are pending in the application, wherein claims 1-4, 7-13, 19-21 and 24-26 have been rejected and claims 5-6 and 22-23 have been withdrawn consequent an Examiner-induced restriction requirement. Claims 1, 19 and 26 have been amended with this paper. Support for the amendments may be found in the Application as originally filed. No new matter has been added. Favorable consideration of the above amendments and following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. § 102

Claims 1, 7-13 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Roll (U.S. Patent No. 5,419,764). Applicant respectfully traverses this rejection.

Independent claim 1 recites, *inter alia*, "a hub assembly connected to the elongate shaft such that the elongate shaft extends distally from the hub assembly" and an interference fit member "configured to form an interference fit with the inner surface of the generally tubular member when the elongate shaft and the interference fit member are disposed within the lumen of the generally tubular member."

Independent claim 26 recites, *inter alia*, "an elongate shaft having a proximal end and a distal end, the proximal end of the elongate shaft being connected to the hub assembly such that the elongate shaft extends distally from the distal end of the hub assembly…wherein the elongate shaft and at least a distal portion of the hub assembly are disposed in the lumen of the generally tubular packaging member such that the interference fit member is engaged with the inner surface of the generally tubular packaging member to form an interference fit with the inner surface of the generally tubular packaging member."

Consistent with terminology used in the instant application including the claims, as well as the terminology generally used by those of skill in the art, the term "proximal" means in a direction or region toward the operator and the term "distal" means in a direction or region away from the operator. The usage of the terms "proximal" and "distal" throughout Roll is consistent with this understanding.

In formulating the rejection, the distal member 104 of the catheter body of Roll is being equated to the claimed hub assembly, and the second tubular portion 113 of the distal member of Roll is being equated to the claimed elongate shaft. In evaluating FIG. 1 of Roll, it is apparent that the second tubular portion 113 extends proximally from the enlarged portion of the distal member 104 into the proximal member 106 of the catheter body 130. This configuration is clearly dissimilar to the configuration currently claimed.

For at least these reasons, Roll does not anticipate either claim 1 or claim 26. Claims 7-13, which depend from claim 1 and which include additional limitations, are also believed patentable over Roll. Withdrawal of the rejection is respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1-4, 7-11, 13, 19-21 and 24-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over McGlinch et al. (U.S. Patent No. 7,214,220), in view of Gadberry et al. (U.S. Patent No. 5,217,114). Applicant respectfully traverses this rejection, asserting a *prima facie* case of obviousness has not been established.

The Office Action admits that McGlinch et al. do not provide all the elements of independent claims 1, 19, and 26. However, the rejection in the Final Office Action stated that "it would have been obvious...to have substituted the IFM (65) including a second material of Gadberry for the IFM (40) of McGlinch in order to create an air tight seal when enclosing the elongate medical device as taught by Gadberry." Final Office Action, February 3, 2009, at paragraph 4. In responding to the Final Office Action, Applicant argued that there is no rationale for combining the O-ring 65 disclosed in Gadberry et al. on the hub assembly of the catheter of McGlinch et al. to provide an air tight seal between the hub assembly of the catheter and the packaging tube. In addressing Applicant's remarks, the Advisory Action indicated that the Office Action "overstated what was needed in suggesting the motivation of creating 'an air tight seal when enclosing the elongate medical device' to substitute the IFM including a second material of Gadberry for the IFM of McGlinch." In a departure from the stated motivation provided in the Final Office Action, the Advisory Action stated that "Essentially, the IFM including a second material of Gadberry is used to form a friction fit between two elements (cap 27 and tube 23); whether the fit is air tight or not is irrelevant."

Applicant respectfully disagrees with this suggestion, asserting that such a suggestion cannot be attained without following an impermissible hindsight analysis. Applicant respectfully maintains that there is no rationale for combining the O-ring 65 disclosed in Gadberry et al. on the hub assembly of the catheter of McGlinch et al. to form a friction fit between the hub assembly of the catheter and the packaging tube as set out in the Advisory Action.[1]

The Manual of Patent Examination Procedure states that "When considering obviousness of a combination of known elements, the operative question is thus 'whether the improvement is more than the predictable use of prior art elements according to their established functions.'" M.P.E.P. §2141 I. The KSR Decision and Principles of the Law of Obviousness, quoting *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

The sole function of the O-ring 65 disclosed in Gadberry et al. is to "form a seal between the cap 27 and housing 25." Gadberry et al., at column 5, lines 35-36. This function of the O-ring 65 is consistent with the established function of an O-ring to one of ordinary skill in the art. See, for example, the entry for "O-ring" from Wikipedia.com, attached herewith, stating that "An O-ring…is a mechanical gasket in the shape of a torus…designed to be seated in a groove and compressed during assembly between two or more parts, creating a seal at the interface."

Dissimilar from the O-ring 65 disclosed in Gadberry et al., the interference fit member as currently claimed creates an interference fit with the packaging tube "to resist gravitational and handling forces that can otherwise cause the [elongated medical] device 20 to fall out of the packaging tube 10 prematurely." Specification, at lines 15-17 of page 7. Thus, the interference fit member as currently claimed functions differently that the established function of the O-ring 65 of Gadberry et al., providing an interference fit with the packaging tube to retain the medical device within the packaging tube notwithstanding any sealing function.

The O-ring 65 disclosed in Gadberry et al. is not a part of the catheter 12 at all. Rather, the O-ring is located at an interface between the cap 27 and the tube 23 of the catheter package 10. At no point do Gadberry et al. suggest the desire to form a fiction fit between the hub 16 of the catheter 12 and the catheter packaging 10. Certainly, the O-ring 65 of Gadberry et al. does not form a friction fit between the hub 16 of the catheter 12 and the catheter packaging 10.

[1] It is noted that Applicant's arguments presented in the Amendment dated March 25, 2009, stating that there is no rationale in either McGlinch et al. or Gadberry et al. to provide an air tight seal between the hub assembly of the catheter and the packaging tube are maintained with this response.

Furthermore, the O-ring 65 of Gadberry et al. does not function to resist the cap 27 from falling off the tube 23 of the catheter package 10. Gadberry et al. disclose specific other structure of the cap 27 and tube 23 to maintain attachment of the cap 27 to the tube 23. Namely, Gadberry et al. state:

> Certainly a primary purpose associated with the housing 25 and the cap 27 is to maintain the catheter 12 in the package 10 until its use is required. Of course it is desirable that the cap 27 also be removable from the housing 25 in order to gain access to the catheter 12.
>
> This removable attachment of the cap 27 to the housing 25 can be accomplished in several manners. The prior art has relied upon sliding the cap axially across a detent. This may provide for a particularly secure fit and is not always easy to accomplish. A preferred motion for separation is a rotation motion which is provide in accordance with the present invention. A screw thread (not shown) could be relied on to rotatably release the cap 27, but in the illustrated embodiment a bayonet fitting shown generally at 110 is provided.

Gadberry et al., at column 5, lines 38-52. Thus, Gadberry et al. disclose a detent, a screw thread, or the bayonet fitting shown in the figures, as providing the means for attaching the cap 27 to the housing 25. One of ordinary skill in the art, in view of the teachings of Gadberry et al., would not perceive the O-ring 65 as a means for maintaining attachment of the cap 27 to the housing 25.

Applicant submits that the difference between the devices of McGlinch et al. and Gadberry et al. discussed herein indicate that a person of ordinary skill in the art would not be inclined to combine McGlinch et al. with Gadberry et al. as proposed in formulating the rejection. Namely, there is no rationale to use the O-ring of Gadberry et al. as an interference fit member between the hub assembly of the catheter and the packaging tube of McGlinch et al., as suggested in formulating the rejection. Applicant asserts that it is only by applying impermissible hindsight using the instant application as a roadmap would the hub assembly of McGlinch et al. be modified by the O-ring of Gadberry et al. as asserted in the Office Action (See for example, *Ruiz v. A.B. Chance Co.*, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004).

For at least the reasons stated above, Applicant believes that a *prima facie* case of obviousness has not been established with the cited combination. Withdrawal of the rejection of claims 1-4, 7-11, 13, 19-21 and 24-26 under §103(a) is respectfully requested.

Claim 12 stands rejected under 35 U.S.C. §103(a) as being unpatentable over McGlinch et al. (U.S. Patent No. 7,214,220), and Gadberry et al. (U.S. Patent No. 5,217,114), and further in

view of Roll (U.S. Patent No. 5,419,764). Applicant respectfully traverses this rejection, asserting a *prima facie* case of obviousness has not been established.

Claim 12 depends from independent claim 1. For at least the reasons stated above regarding the allowability of claim 1, Applicant submits that claim 12 is also allowable. Withdrawal of the rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
John Moberg
By his Attorney,

Date: June 1, 2009

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Attachment: O-ring entry from Wikipedia (four sheets)

O-ring

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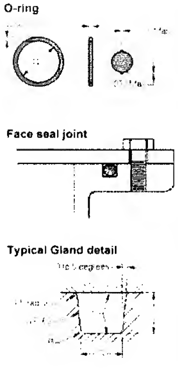
From Wikipedia, the free encyclopedia

An **O-ring**, also known as a packing, or a **toric joint**, is a mechanical gasket in the shape of a torus; it is a loop of elastomer with a disc-shaped cross-section, designed to be seated in a groove and compressed during assembly between two or more parts, creating a seal at the interface.

The joint may be static, or (in some designs) have relative motion between the parts and the O-ring; rotating pump shafts and hydraulic cylinders, for example. Joints with motion usually require lubrication of the O-ring to reduce wear. This is typically accomplished with the fluid being sealed.

O-rings are one of the most common seals used in machine design because they are inexpensive and easy to make, reliable, and have simple mounting requirements. They can seal tens of megapascals (thousands of psi) pressure.



Typical O-ring and application

Contents

History

The O-ring U. S. patent claim was filed in 1937 by a then 72 year old Danish-born machinist, Niels Christensen [1]. He came to America in 1891 and soon after that patented an air brake system for streetcars. Despite his legal efforts, his intellectual property rights were passed from company to company until they ended up at Westinghouse [2]. During World War II, the US government commandeered the O-ring patent as a critical war-related item and gave the right to manufacture to other organizations. Christensen got a lump sum payment of US$75,000 for his efforts. Litigation resulted in a $100,000 payment to his heirs in 1971, 19 years after his death.

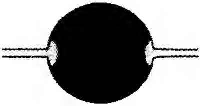
Theory and design

O-rings are one of the most common yet important elements of machine design.
They are available in various metric and standard sizes. The UK standards sizes are
known as BS Sizes and typically range from BS001 to BS932. The most common standard sizes in the US are controlled by SAE AS568A. In general O-rings are specified by the inside diameter and the cross section diameter (thickness). The O-ring is one of the simplest, yet most engineered, precise, and useful seal designs ever developed.

Typical applications

Successful O-ring joint design requires a rigid mechanical mounting that applies a predictable deformation to the O-ring. This introduces a calculated mechanical stress at the O-ring contacting surfaces. As long as the pressure of the fluid being contained does not exceed the contact stress of the O-ring, leaking cannot occur.

The seal is designed to have a point contact between the O-ring and sealing faces. This allows a high local stress, able to contain high pressure, without exceeding the yield stress of the O-ring body. The flexible nature of O-ring materials accommodates imperfections in the mounting parts. Maintaining good surface finish of those mating parts is still important, however, especially at low temperatures where the seal rubber reaches its glass transition temperature and becomes increasingly crystalline.



O-ring mounting for an ultra-high vacuum application. Pressure distribution within the cross-section of the O-ring. The red lines are hard surfaces, which apply high pressure. The fluid in the seams has lower pressure. The soft O-ring bridges the pressure over the seams.

Vacuum applications

In vacuum applications the permeability of the material makes point contacts quite useless. Instead, higher mounting forces are used and the ring fills the whole groove. Also round back-up rings are used to save the ring from excessive deformation [3] [4] [5]. As the ring feels the ambient pressure only at the seals and the ring feels the partial pressure of gases only at the seal, their gradients will be steep near the seal and shallow in the bulk (opposite to the gradients of the point contact [6]). See: Vacuum_flange#KF.2FQF. For high vacuum systems below 10^{-9} Torr, copper or nickel O-rings have to be utilized. As rubber becomes hard and brittle at low temperatures, in vacuum systems that have to be immersed in liquid nitrogen, indium O-rings are used.

High temperature applications

In some high temperature applications, O-rings may need to be mounted in a tangentially compressed state to compensate for the Gow-Joule effect.

Material

O-ring selection is based on chemical compatibility [7], application temperature [8], sealing pressure [9], lubrication requirements, quality, quantity and cost.

Some small O-rings

Synthetic rubbers - Thermosets:

- Butadiene rubber (BR)
- Butyl rubber (IIR)
- Chlorosulfonated polyethylene (CSM)
- Epichiorohydrin rubber(ECH, ECO)
- Ethylene propylene diene monomer (EPDM)
- Ethylene propylene rubber (EPR)
- Fluoroelastomers (FKM)
- Nitrile rubber (NBR)
- Perfluoroelastomer (FFKM)
- Polyacrylate rubber(ACM)
- Polychloroprene (CR)
- Polyisoprene (IR)
- Polysulfide rubber (PSR)
- Silicone rubber (SiR)
- Styrene butadiene rubber (SBR)

Thermoplastics:

- Thermoplastic elastomer (TPE) styrenics
- Thermoplastic polyolefin (TPO) LDPE, HDPE, LLDPE, ULDPE
- Thermoplastic polyurethane (TPU) polyether, polyester
- Thermoplastic etheresterelastomers (TEEEs) copolyesters
- Thermoplastic polyamide (PEBA) Polyamides
- Melt Processible Rubber (MPR)
- Thermoplastic Vulcanizate (TPV)

Other seals

There are variations in cross-section design other than circular. These include O-rings with x shaped profiles, commonly called x-rings or quad rings. When squeezed upon installation, they seal with 4 contact surfaces – 2 small contact surfaces on the top and bottom. This contrasts with the O-ring's comparatively larger single contact surfaces top and bottom. X-rings are most commonly used in reciprocating applications, where they provide reduced running and breakout friction and reduced risk of spiraling when compared to O-rings.

There are also O-rings with a square profile, commonly called square-cut. When O-rings were selling at a premium because of the novelty, lack of efficient manufacturing processes and high labor content, square-cuts were introduced as an economical substitution for O-rings. The square-cut is manufactured by molding an elastomer sleeve which is then lathe-cut. This style of seal is sometimes less expensive to manufacture with certain materials and molding technologies (compression, transfer, injection), especially in low volumes. The physical sealing performance of square-cut rings is inferior to the O-rings. Today the price of O-rings has decreased to the point that the square-cut design is nearly obsolete.

Similar devices with a non-round cross-sections are called seals or packings. See also washer (mechanical).

Failure modes of O-rings

O-ring materials may be subjected to high or low temperatures, chemical attack, vibration, abrasion, and movement. Materials are selected according to the situation.

O-ring materials exist which can tolerate temperatures as low as -200 C or as high as 250+ C. At the low end nearly all engineering materials will turn rigid and fail to seal, at the high end the materials will often burn or decompose. Chemical attacks can degrade the material, start brittle cracks or cause it to swell. For example, NBR seals can crack when exposed to ozone gas at very low concentrations unless protected. Other failures can be caused by using the wrong size of ring for a specific recess, when extrusion of the rubber will occur.

Challenger disaster

The failure of an O-ring seal was determined to be the cause of the Space Shuttle *Challenger* disaster on January 28, 1986. A contributing factor was cold weather prior to the launch. This was famously demonstrated on television by Caltech physics professor Richard Feynman, when he placed a small O-ring into ice-cold water, and subsequently showed its loss of pliability before an investigative committee.

O-rings are now examined under high-power video microscopes for defects

The material of the failed O-ring was FKM which was specified by the shuttle motor contractor, Morton-Thiokol. FKM is not a good material for cold temperature applications. When an O-ring is cooled below its T_g (glass transition temperature), it loses its elasticity and becomes brittle. More importantly, when an O-ring is cooled near, but not beyond, its T_g, the cold O-ring, once compressed, will take longer than normal to return to its original shape. O-rings (and all other seals) work by creating positive pressure against a surface thereby preventing leaks. On the night before the launch, exceedingly low air temperatures were recorded. On account of this, NASA technicians performed an inspection. The ambient temperature was within launch parameters, and the launch sequence was allowed to proceed. However, the temperature of the rubber O-rings remained significantly lower than that of the surrounding air. During his investigation of the launch footage, Dr. Feynman observed a small out-gassing event from the Solid Rocket Booster (SRB) at the joint between two segments in the moments immediately preceding the explosion. This was blamed on a failed O-ring seal. The escaping high temperature gas impinged upon the external tank, and the entire vehicle was destroyed as a result.

The rubber industry has gone through its share of transformation after the accident. Many O-rings now come with batch and date coding, as in the medicine industry, to precisely track and control distribution. O-rings can, if needed, be recalled off the shelf. [10] Furthermore, O-rings and other seals are routinely batch-tested for quality control by the manufacturers, and often undergo Q/A several more times by the distributor and ultimate end users.

As for the SRBs themselves, NASA and Morton-Thiokol redesigned them with a new joint design, which now incorporated three

O-rings instead of two, with the joints themselves having onboard heaters which can be turned on when temperatures drop below 50 °F (10 °C). No O-ring issues have occurred since *Challenger*, and they did not play a role in the Space Shuttle Columbia disaster of 2003.

Future of the O-Ring

An O-ring is one of the most simple, yet highly critical, precision mechanical components ever developed. However, there are new advances that may take some of the burden of critical sealing away from the exclusive domain of O-rings. There are cottage industries of elastomer consultants assisting in designing O-ring-less pressure vessels. Nano-rubber is one such new frontier. Presently these advancements are increasing the importance of O-rings. Since O-rings encompass the areas of chemistry and material science, any advancement in nano-rubber will affect the O-ring industry.

Already there are elastomers filled with nano-carbon and nano-PTFE and molded into O-rings used in high performance applications. For example carbon nanotubes are used in electrostatic dissipative applications and nano-PTFE is used in ultra pure semiconductor applications. The use of nano-PTFE in fluoroelastomers and perfluoroelastomers such as Viton improves abrasion resistance, lowers friction, lowers permeation, and can act as clean filler.

Using conductive carbon black or other fillers can exhibit the useful properties of conductive rubber, namely preventing electrical arcing, static sparks, and the overall build-up of charge within rubber that may cause it to behave like a capacitor (electrostatic dissipative). By dissipating these charges, these materials, which include doped carbon-black and rubber with metal filling additives, reduce the risk of ignition, which can be useful for fuel lines.

O-ring standards

ISO 3601 Fluid power systems -- O-rings

- ISO 3601-1:2008 Inside diameters, cross-sections, tolerances and designation codes
- ISO 3601-2:2008 Housing dimensions for general applications
- ISO 3601-4:2008 Anti-extrusion rings (back-up rings)

See also

- Kremer's O-Ring Theory of Economic Development
- Labyrinth seal
- Ozone cracking
- Polymer degradation
- Diaphragm seal

References

- Designing with Fluoroelastomers
- University of Houston Article on Niels Christensen
- "Dichtomatik O-ring handbook", written at an introductory level
- Standard (AS568), Metric, and Special (JIS, etc) Sizes
- Popular O-ring Materials
- O-Rings Shelf Life Reference
- Standard (AS568), Metric, Swedish (SMS), French and JIS Sizes